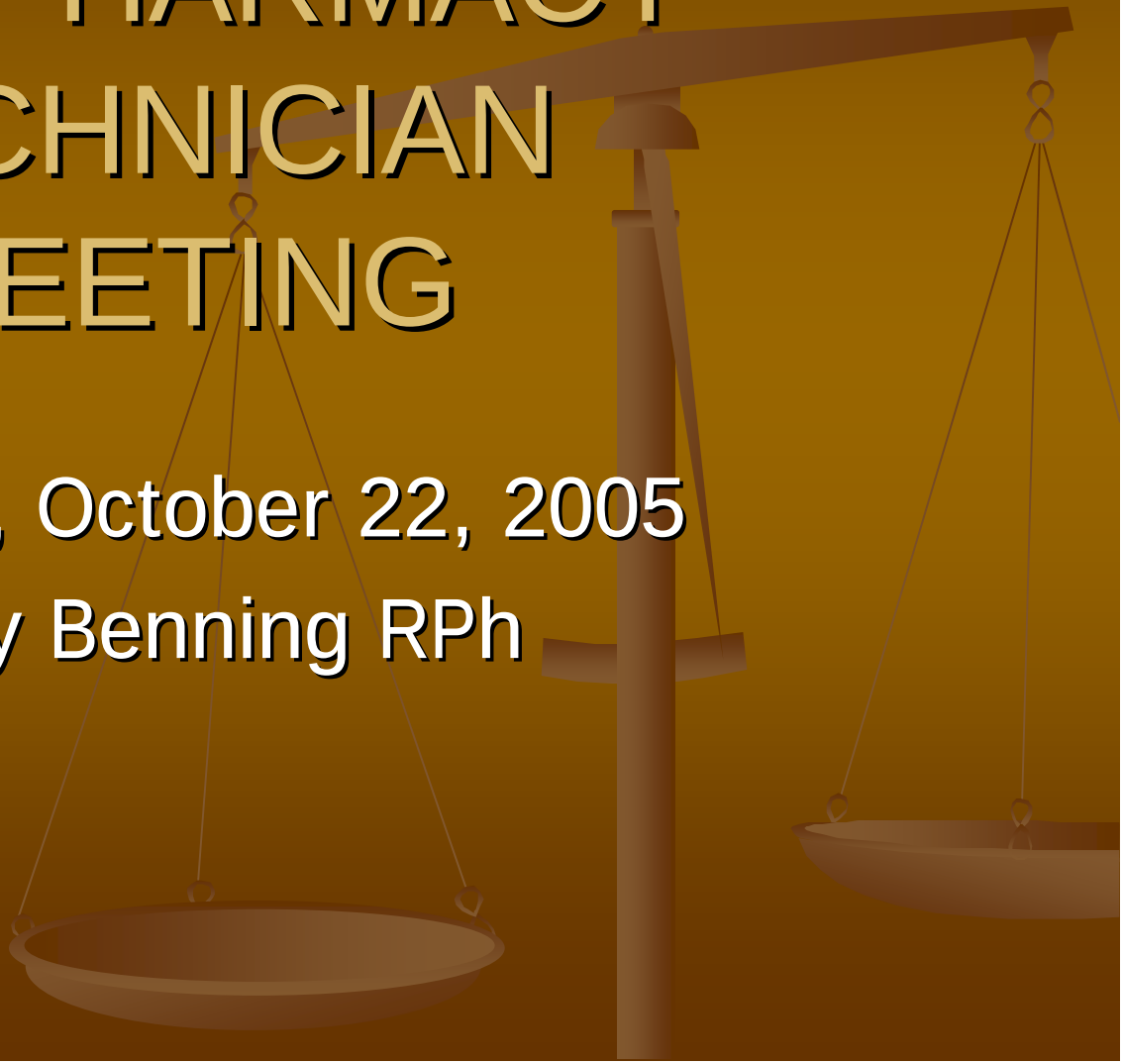
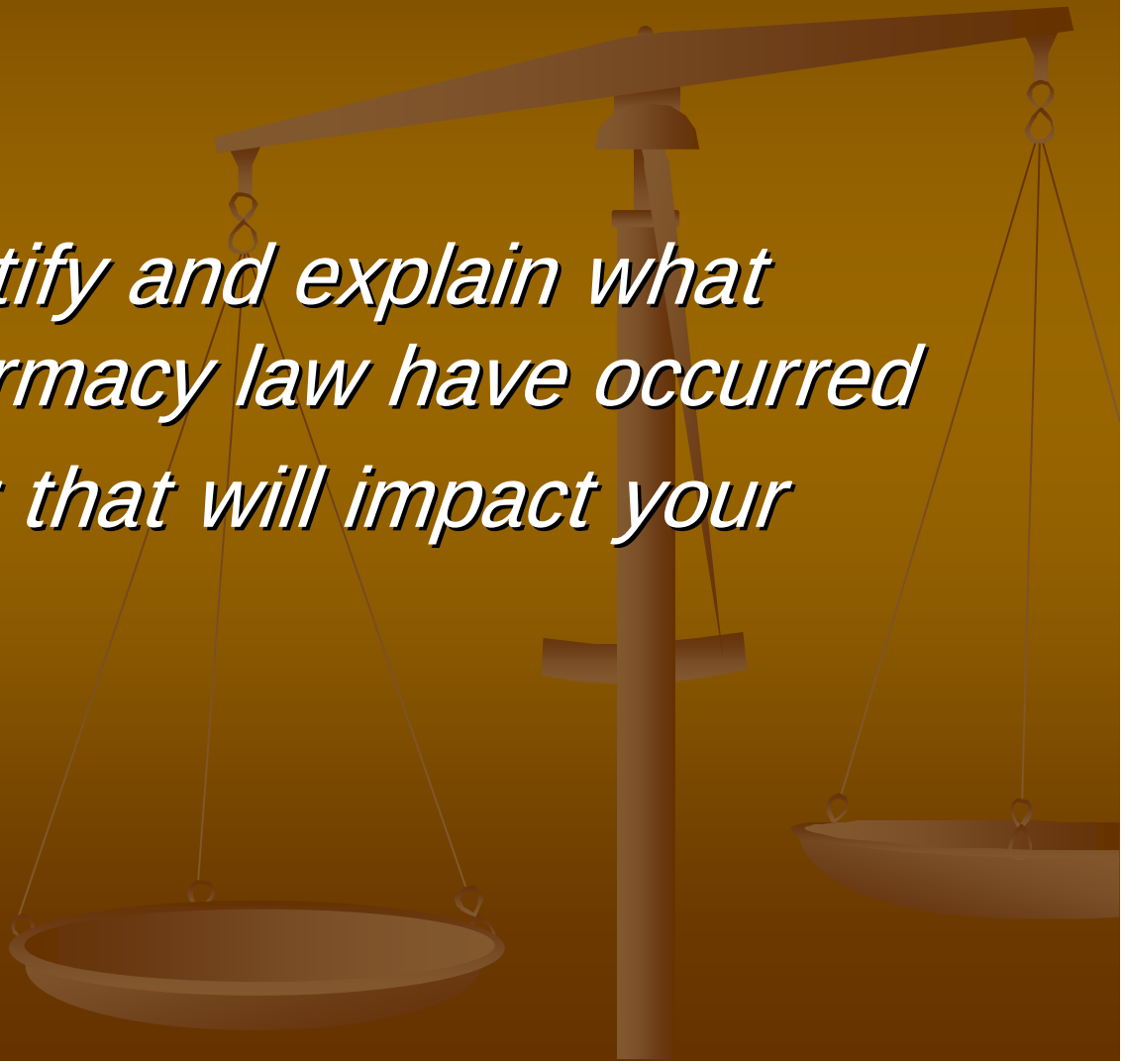
PSW PHARMACY TECHNICIAN MEETING

Saturday, October 22, 2005

Cindy Benning RPh



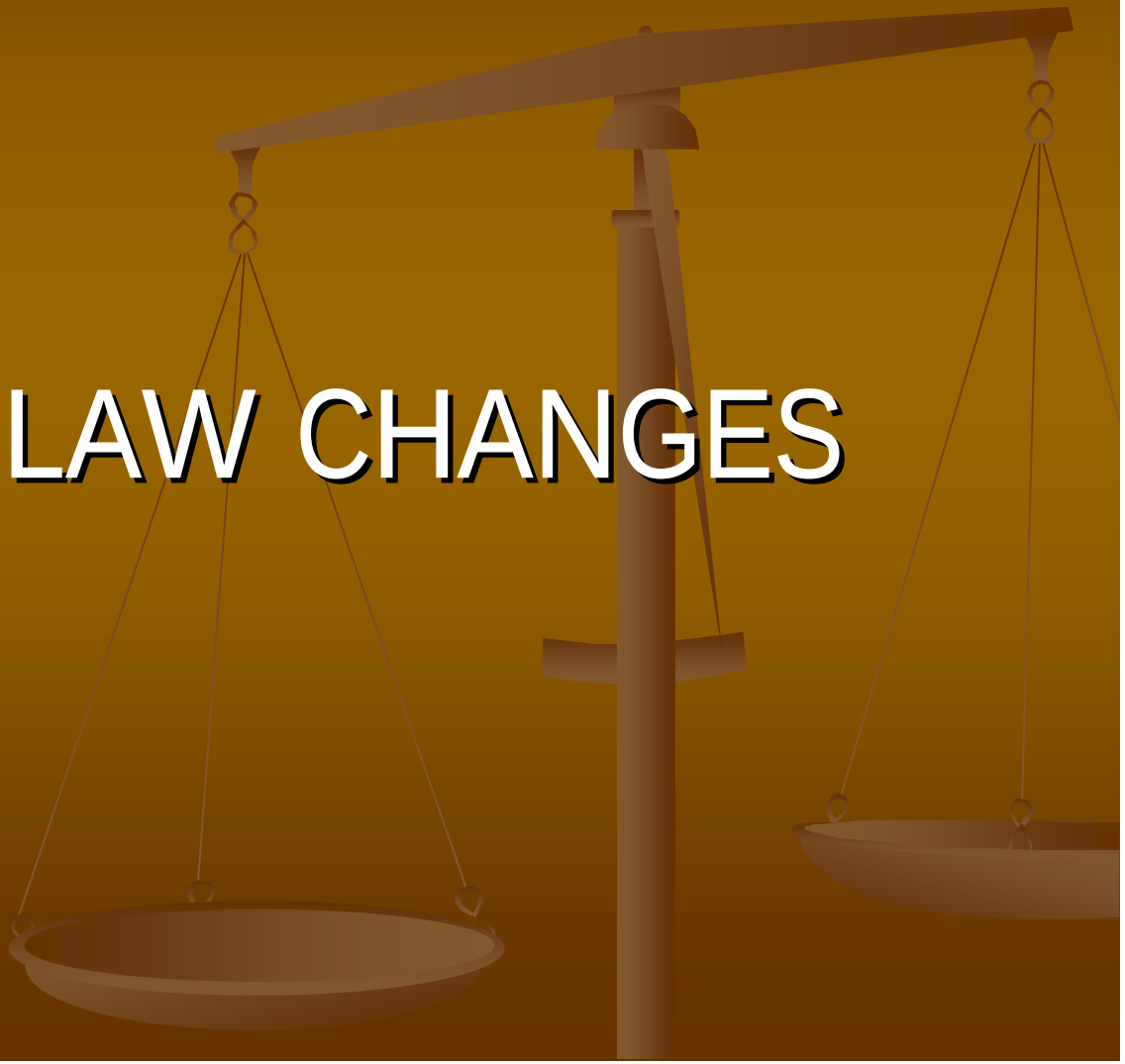
PHARMACY EXAMINING BOARD UPDATE



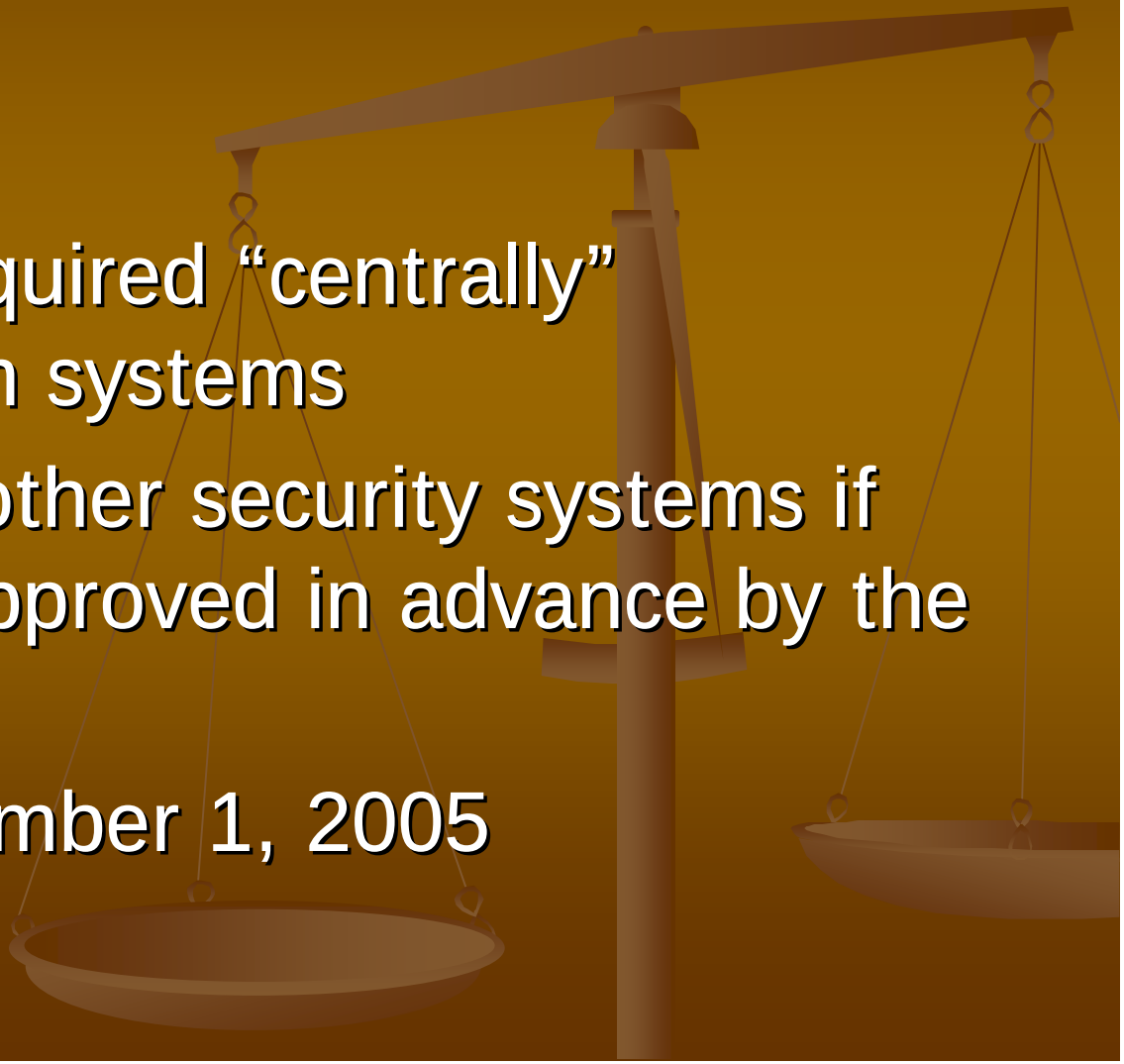
Objective: Identify and explain what changes to pharmacy law have occurred in the past year that will impact your practice

- *State laws*
- *Federal laws*

STATE LAW CHANGES



Pharmacy Security Systems



- Pharm 6.08
- Previous law required “centrally” monitored alarm systems
- Change allows other security systems if reviewed and approved in advance by the board
- Effective September 1, 2005

RETURN OF HEALTH CARE ITEMS

- Pharm 7.04
- Allows the return of health care items from “resident health care patients”
  - Patient residing in a community-based residential facility that controls a resident’s prescribed and over-the-counter medications
  - May only be returned to the pharmacy from which it was dispensed or sold

RETURN OF HEALTH CARE ITEMS

- The health item was never in the possession of the patient
- The health item was dispensed in a tamper-resistant package
- The health item will not be commingled with a different health item
- The health item is in it’s original container and the pharmacist determines the contents are not adulterated or misbranded

RETURN OF HEALTH CARE ITEMS

- Allows returns from “secured institutional health care patients”
  - A jail inmate whose dispensed health care items are maintained under the custody of the jail
  - A juvenile patient who resides in a secured correctional facility, a secured child caring institution, a secured group home, a secured detention facility or a juvenile portion of a county jail

RETURN OF HEALTH CARE ITEMS

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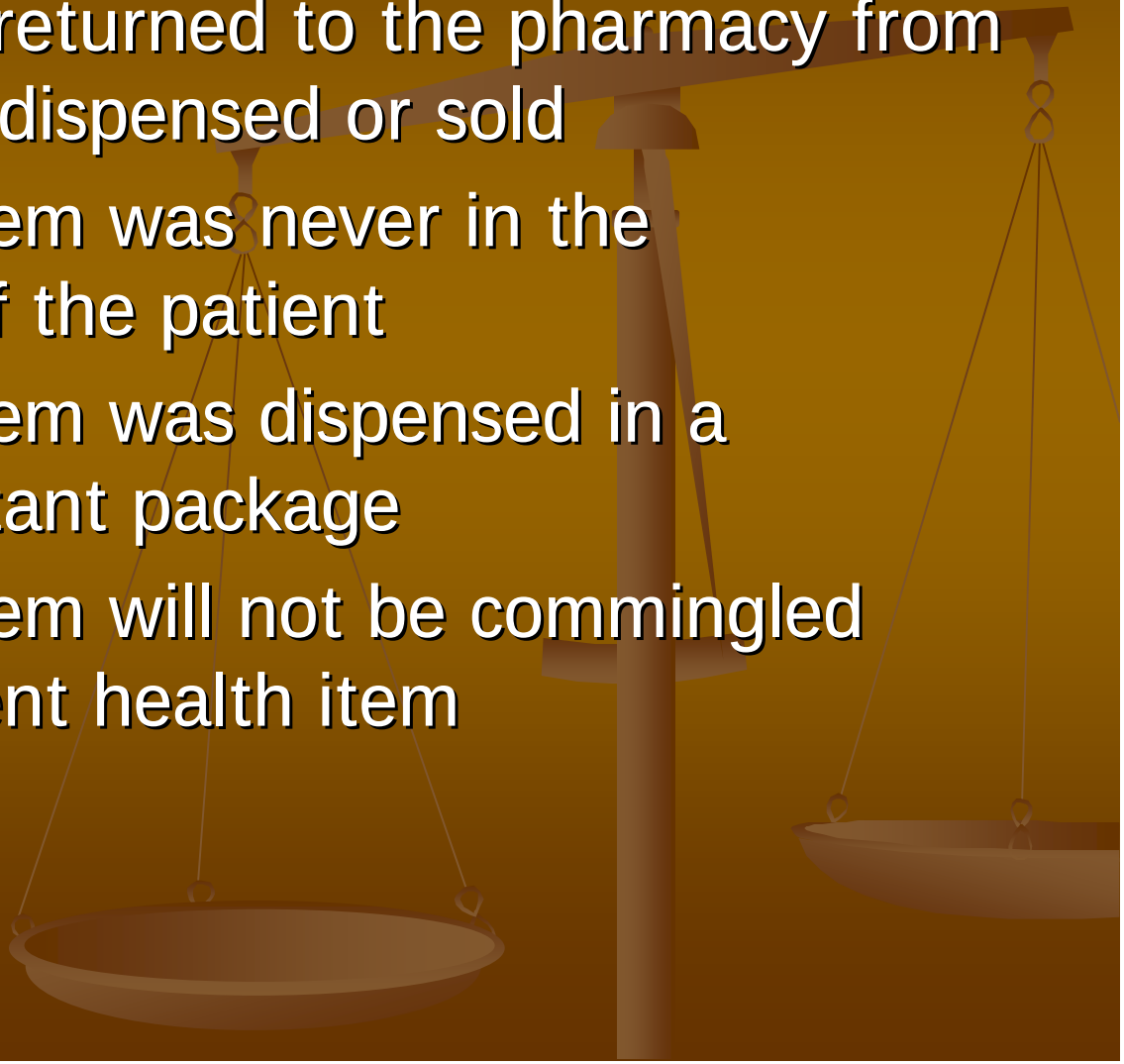
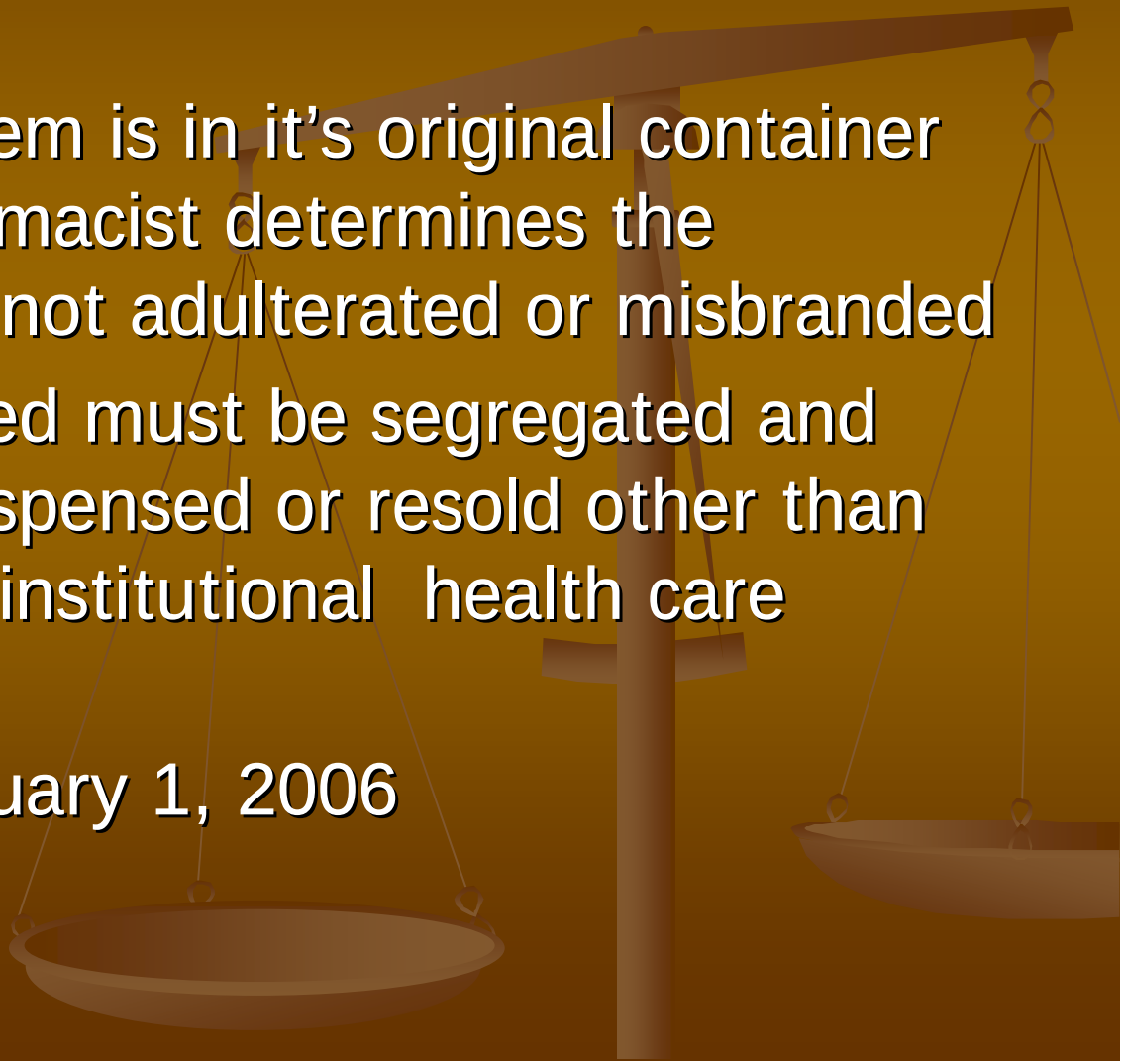


RETURN OF HEALTH CARE ITEMS



- The health item is in it's original container and the pharmacist determines the contents are not adulterated or misbranded
- Items returned must be segregated and may not redispensed or resold other than to a secured institutional health care patient
- Effective January 1, 2006

Cancer Drug Repository

- Anyone may donate a cancer drug or supply
- Recipient must meet specific criteria
- Medical facilities or pharmacies may participate if they meet requirements
- Eligible facilities/pharmacies may distribute drug between each other

Cancer Drug Repository

- The medical facility or pharmacy may charge a handling charge
- Items must be in their original, unopened, sealed and tamper-evident unit dose packaging
- The item must bear an expiration date that is more than 6 months after the item was donated

Cancer Drug Repository

- Drugs or supplies are not misbranded or adulterated as determine by a pharmacist
- Drugs must be prescribed by a practitioner
- Drugs must be dispensed by a pharmacist
- Non of the drugs or supplies may be resold
- The manufacturer is not liable

Cancer Drug Repository

- Others involved in the process are not liable or guilty of unprofessional conduct if there was not intentional misconduct
- Medical facilities and pharmacies must have standards and procedures for accepting, storing, inspecting and dispensing

Cancer Drug Repository

- Prioritization goes to uninsured or indigent patients
- Patients must have some sort of identification, such as a card
- Maximum fee for accepting, distributing and dispensing donated medications is 350% of the Medicaid dispensing fee
- There will be list of drugs and supplies that the repository will and will not accept

Chronic Disease Repository

- Same criteria as the cancer drug repository
- Chronic disease defined as: a disease, illness, impairment or other physical condition, other than cancer, that requires health care and treatment over a prolonged period and, although amenable to treatment, frequently progresses to increasing disability or death

Repositories: What to know

- Your pharmacy must have elected to participate and meet the criteria
- The drugs or supplies must be in original, unopened, sealed, tamper-evident unit-dose packaging
- They must be determined to not be adulterated or misbranded
- They must have an expiration date greater than 6 months from the time donated

Pseudoephedrine Legislation

- Pseudoephedrine and ephedrine are drugs needed for the manufacture of clandestine methamphetamine
- Ephedrine has been a scheduled IV for some time
- Legislation was designed to limit the access to pseudoephedrine
- Needed to also assure access for legitimate use as a medication

Pseudoephedrine Legislation

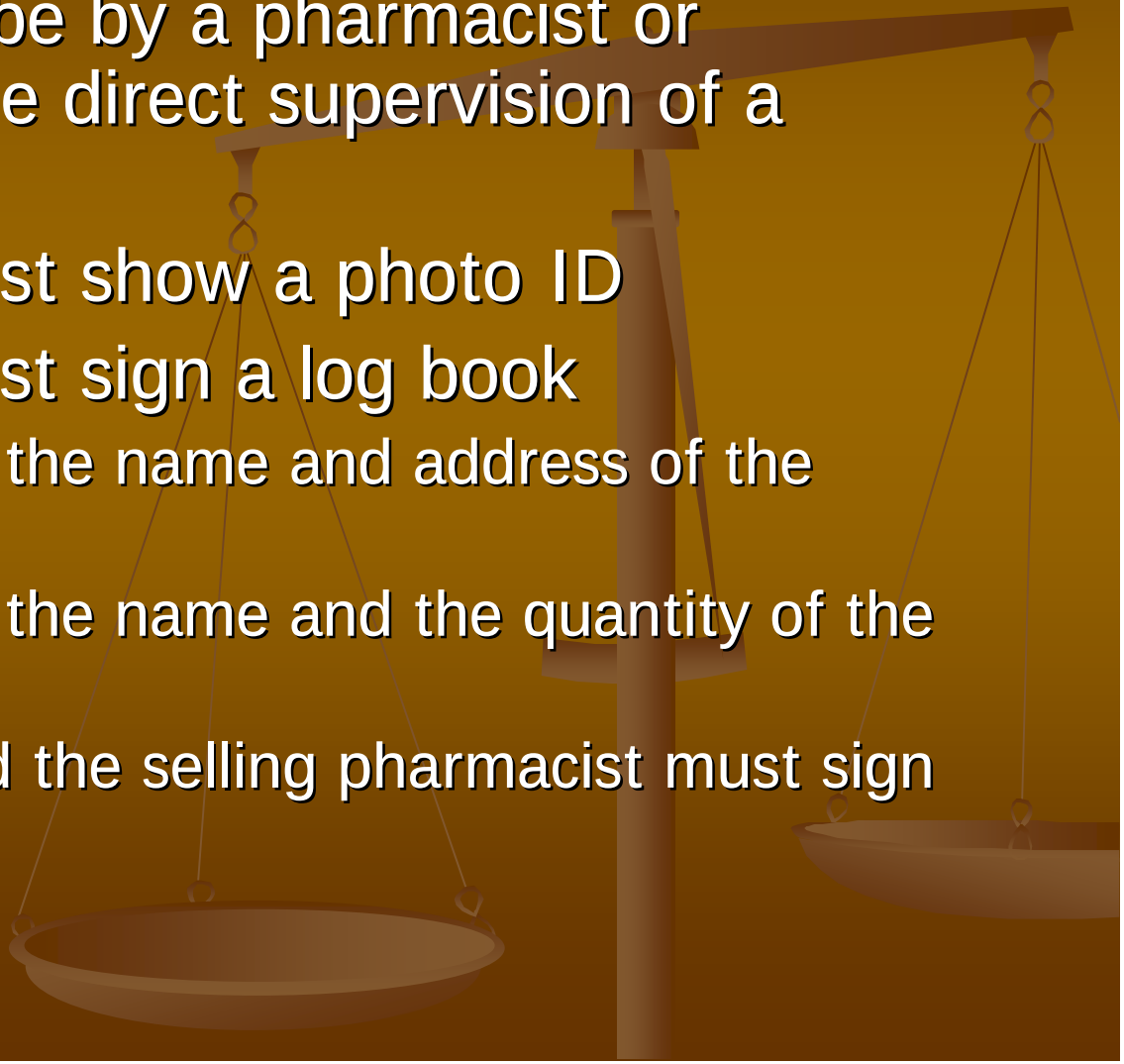
- Other states around the country were passing legislation to restrict pseudoephedrine sales.
- The number of clandestine meth labs has been increasing every year
- There was beginning to be discussion about federal legislation to restrict the sale of pseudoephedrine

Pseudoephedrine Legislation

- Restricted sales applies to all single ingredient pseudoephedrine and any combination products containing pseudoephedrine
- It makes these products schedule V drugs
- Liquid and gel cap pseudoephedrine products are not included
- Sale of restricted items is limited to pharmacies

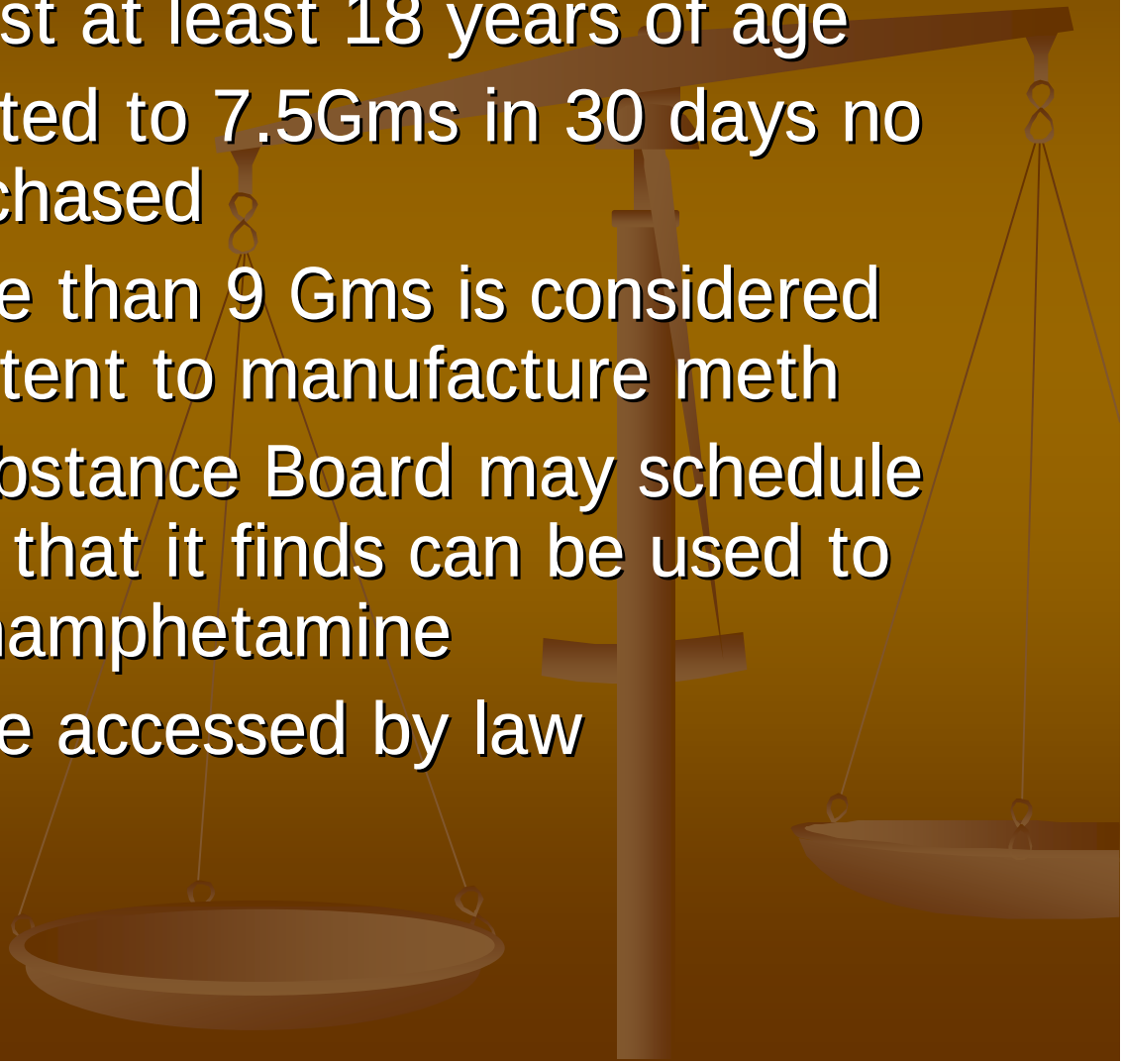
Pseudoephedrine Legislation

- Distribution must be by a pharmacist or someone under the direct supervision of a pharmacist
- The purchaser must show a photo ID
- The purchaser must sign a log book
  - Seller shall record the name and address of the purchaser
  - Seller shall record the name and the quantity of the product sold
  - The purchaser and the selling pharmacist must sign the log

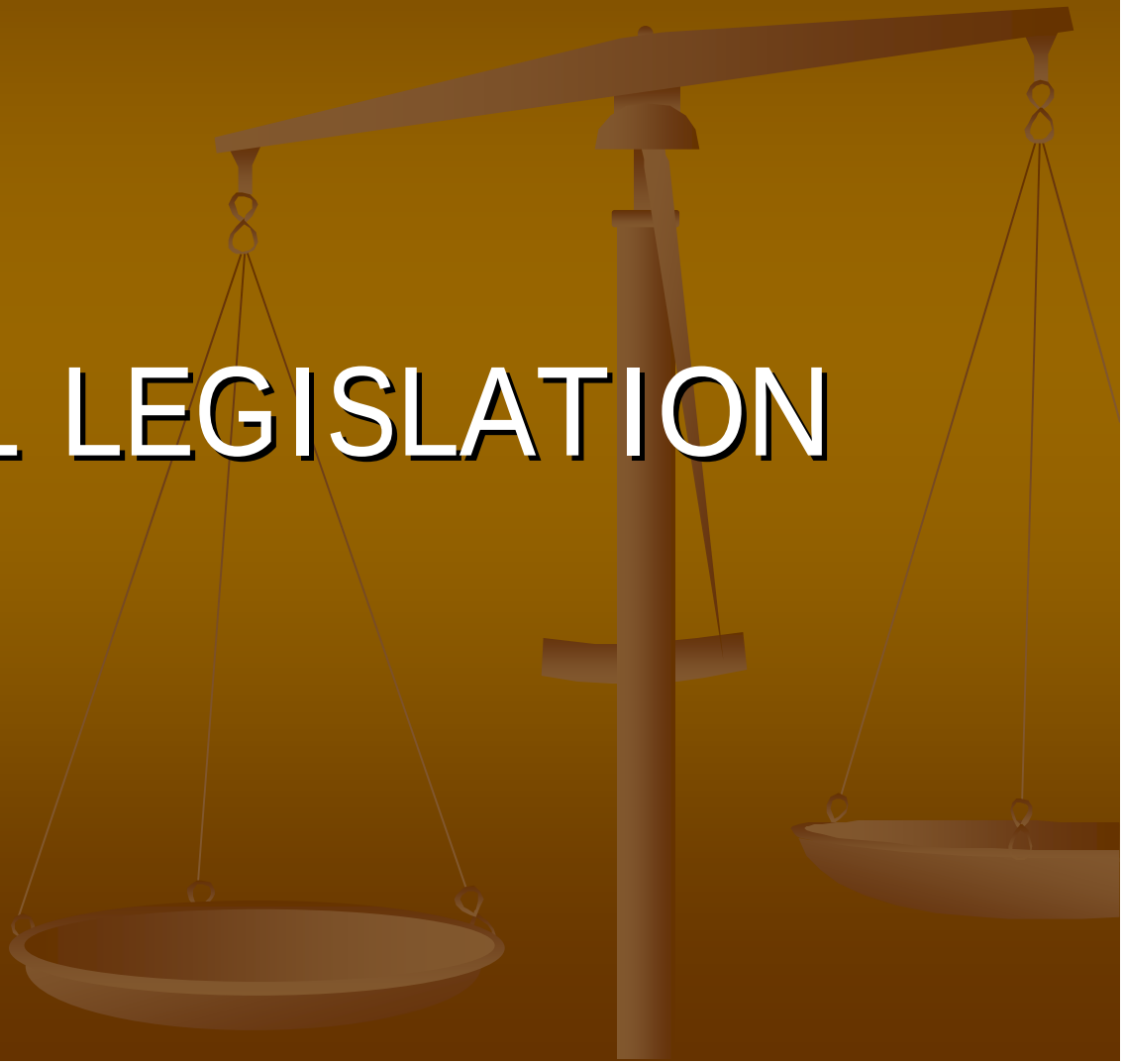


Pseudoephedrine Legislation

- The purchaser must at least 18 years of age
- Purchases are limited to 7.5Gms in 30 days no matter where purchased
- Possession of more than 9 Gms is considered possession with intent to manufacture meth
- The Controlled Substance Board may schedule any other product that it finds can be used to manufacture methamphetamine
- Logs are able to be accessed by law enforcement



FEDERAL LEGISLATION



Schedule II Prescriptions

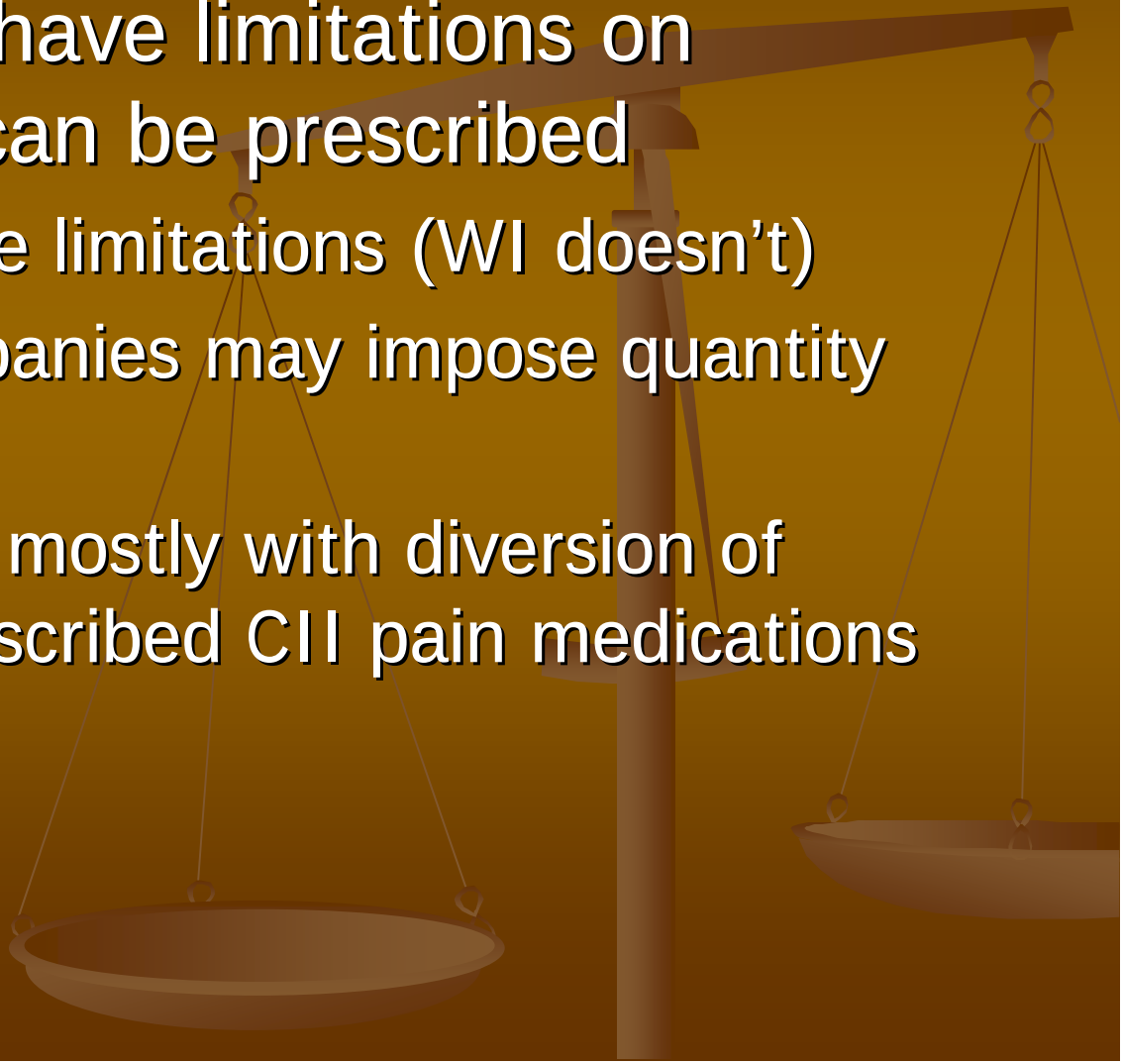
- Change in DEA interpretation of legality of patient getting multiple CII Rx's at one MD visit
- Patients could 3 CII Rx's (3 months worth) as long as all filled within 60 days
- DEA now considering this a "refill"
- DEA published an interim statement that allowed for public comment

Schedule II Prescriptions

- Comments did not cause them to reverse their interpretation
- DEA suggests that MD's mail patient's CII RX's for ongoing therapy
- Alternative would be to fax them to the pharmacy
  - Patient must still bring in original before dispensing

Schedule II Prescriptions

- DEA does not have limitations on quantities that can be prescribed
  - States may have limitations (WI doesn't)
  - Insurance companies may impose quantity limitations
  - DEA concerned mostly with diversion of legitimately prescribed CII pain medications



Schedule II Prescriptions

- Suggestions for how to help patients
  - Suggest they keep the prescriptions in their possession and bring in monthly
  - Suggest they keep the prescriptions in their possession and mail to the pharmacy monthly
  - Suggest the MD mail the prescriptions to the pharmacy monthly
  - If multiple prescriptions written on same date, all must be filled within 60 days

Federal Theft and Loss

- Effective September 12, 2005
- DEA must be notified in writing of any theft or significant loss within one business day of discovery
- “significant” is based on:
  - actual quantity
  - the specific controlled substance
  - what type of access there is to the substance
  - if there is a pattern of loss

Federal Theft and Loss

- whether the substance is a likely candidate for diversion
- Local trends for the potential for diversion of the substance

- The supplier is responsible for reporting all in-transit losses of controlled substances by a common carrier or contract carrier
- Notification must be within 1 business day of discover of theft or loss

CHANGES ON THE HORIZON

Responses to Hurricanes

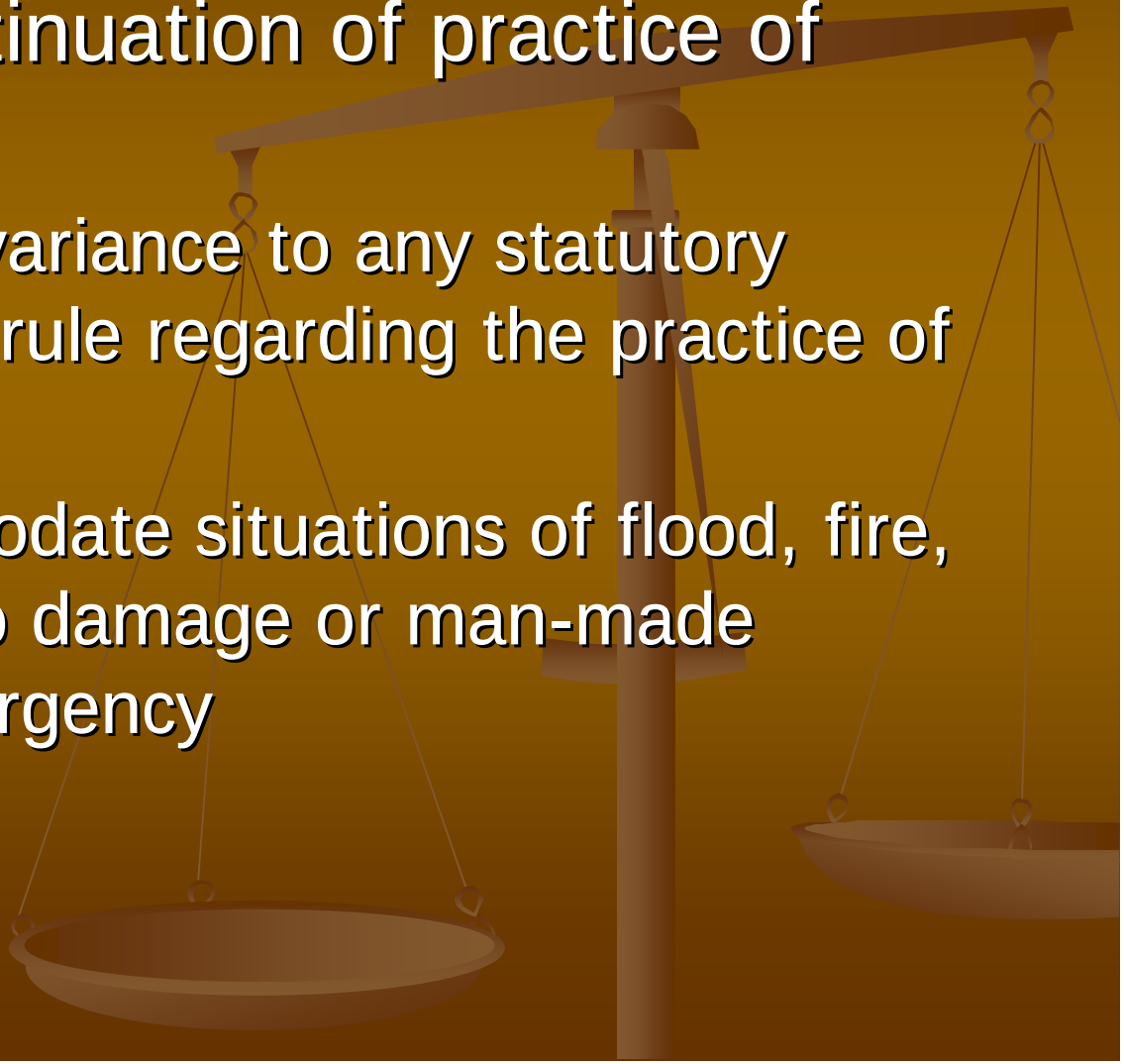
- PEB will allow pharmacists licensed in affected states to get expedited licenses to practice pharmacy in Wisconsin
  - Look at status of current licensure in home state
  - Assess level of active practice in home state
  - Temporary licensure

Responses to Hurricanes

- PEB allows pharmacists to fill prescriptions off of prescription bottle labels for controlled and non-controlled medications
  - To the extent necessary
  - RPh determines prescription is valid
  - For a limited and reasonable time
  - Applies to residents of Louisiana, Mississippi, Alabama and Florida

Changes on the Horizon

- Emergency continuation of practice of pharmacy
  - Would allow a variance to any statutory requirement or rule regarding the practice of pharmacy
  - Would accommodate situations of flood, fire, wind or tornado damage or man-made disaster or emergency



Changes on the Horizon

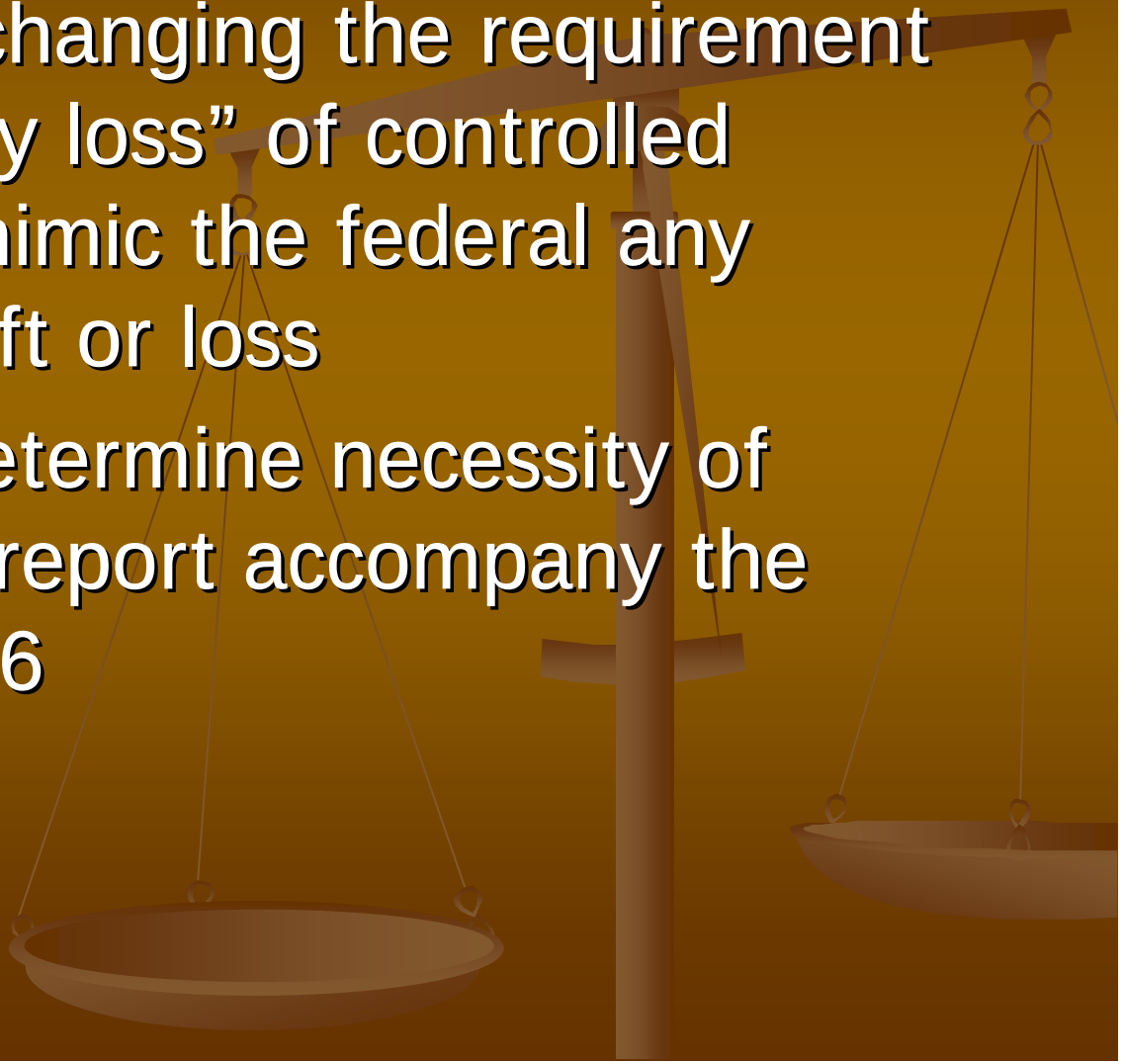
- Emergency continuation of the practice of pharmacy
  - The board determines a variance is necessary to protect the public health, safety and welfare
  - The board determines that a disaster or emergency exists
  - The pharmacist must request the variance
  - Term of the variance will be 90 days unless an extension requested by the pharmacist and approved by the board

Changes on the Horizon

- Licensure of out-of-state pharmacies
  - Would allow investigation and discipline of pharmacies that deliver, mail or ship prescription drugs into the state of Wisconsin
  - Assures out-of-state pharmacies are familiar with Wisconsin laws and regulations
  - Does not require out-of-state pharmacists to be licensed in Wisconsin

Changes on the Horizon

- PEB looking at changing the requirement of reporting “any loss” of controlled substances to mimic the federal any “significant” theft or loss
- Also trying to determine necessity of having a police report accompany the Federal form 106



Information

- DEA Pharmacist's Manual
- Last printed 2001
- April 2004 version available on the web and downloadable in a PDF file
- www.deadiversion.usdoj.gov
  - Go to links to publications
  - Go to link to manuals